

What is claimed is:

[Claim 1] 1. A chromatographic assay device for the analysis of an analyte in a liquid sample, said device comprising:

- a) chromatographic medium having a proximal sample application zone and a distal test zone, in which the test zone contains a first ligand capable of binding with the analyte to form an analyte–ligand complex;
- b) a spatially distinct reservoir containing a labeled reagent capable of binding to the analyte–ligand complex;
- c) an absorbent sink which is positioned to be capable of drawing the contents of the spatially distinct reservoir through the test zone; and
- d) means for contacting the spatially distinct reservoir with the chromatographic medium so that the labeled reagent migrates from the reservoir to the absorbent sink, and thereby through the test zone to determine the presence or absence of the analyte.

[Claim 2] The assay device of claim 1 wherein the labeled reagent is labeled with a colloidal particle.

[Claim 3] The assay device of claim 1 wherein the labeled reagent is labeled with gold.

[Claim 4] The assay device of claim 1 wherein the first ligand is an unlabelled capture antibody.

[Claim 5] The assay device of claim 4 wherein the labeled reagent is a detection antibody.

[Claim 6] A chromatographic assay device for the analysis of at least one analyte in a liquid sample, said device comprising:

- a) a chromatographic medium having a proximal sample application zone and a distal test zone, in which the test zone contains a first ligand capable of binding with the analyte to form an analyte–ligand complex;
- b) at least one spatially distinct reservoir containing a labeled reagent capable of binding to the analyte–ligand complex;
- c) at least one absorbent sink which is positioned to be capable of drawing the contents of the at least one spatially distinct reservoir through the test zone; and
- d) means for contacting the spatially distinct reservoir with the chromatographic medium so that the labeled reagent migrates from the reservoir to the absorbent sink, and thereby through the test zone to determine the presence or absence of the analyte.

[Claim 7] The assay device of claim 6 wherein the labeled reagent is labeled with a colloidal particle.

[Claim 8] The assay device of claim 6 wherein the labeled reagent is labeled with gold.

[Claim 9] The assay device of claim 6 wherein the first ligand is an unlabelled capture antibody.

[Claim 10] The assay device of claim 9 wherein the labeled reagent is a detection antibody.

[Claim 11] A method for determining the presence or absence of at least one analyte in a liquid sample comprising the steps of:

- a) providing a chromatographic assay device comprising a chromatographic medium having a test zone containing at least one immobilized ligand capable of binding the analyte and thereby forming a ligand–analyte pair, and further comprising at least one spatially distinct reservoir containing a labeled reagent capable of binding to the ligand–analyte pair, and further comprising an absorbent sink;
- b) contacting the liquid sample with the proximal end of the chromatographic medium such that the sample is chromatographically transported to a distal test zone, and thereby forming a ligand–analyte pair;

c) contacting the labeled reagent and the absorbent sink with the chromatographic medium to chromatographically draw the labeled reagent through the test zone.

[Claim 12] The method of claim 11 in which the liquid sample is selected from the group consisting of blood, urine, and saliva.

[Claim 13] The method of claim 11 in which the liquid sample is blood.

[Claim 14] An analytical test device suitable for determining the presence, absence, or quantity of an analyte in a liquid sample said device comprising a housing which contains:

- (a) a first component which is a chromatographic test strip through which the sample flows by capillary action from a sample application zone to contact a downstream test zone on the test strip, said downstream test zone containing an unlabelled immobile first reactant which reacts with the analyte if present to form an unlabelled reactant/analyte product;
- (b) a second component separated from the first component and carrying a second, mobilizable, labeled reactant which is so placed on as to be moved into contact with the unlabelled reactant/analyte product to form a detectable unlabelled reactant/analyte/labeled reactant complex;

said first reactant and said second reactant being initially separate but in a spatial relationship such that they can be brought together after formation of the unlabelled reactant/analyte product to permit the reaction which forms the detectable unlabelled reactant/analyte/unlabelled reactant complex.

[Claim 15] A device as in claim 14 including an absorbent sink on one of the components to facilitate the capillary movement of the liquid sample.

[Claim 16] A device as in claim 14 wherein the label is a colloidal particle label.

[Claim 17] A device as in claim 14 wherein the label is gold.

[Claim 18] A device as in claim 14 wherein the first reactant is an unlabelled capture antibody and the analyte is an antigen which the antibody binds to form a reaction product.

[Claim 19] A device as in claim 18 wherein the second reactant is a labeled detection antibody which forms a complex with the reaction product.

[Claim 20] A device as in claim 19 wherein the label is gold.

[Claim 21] A method for determining the presence, absence or quantity of at least one analyte in a liquid sample comprising the steps of:

- a) providing an assay device comprising a housing which contains
 - i. a first component which is a chromatographic test strip through which the sample flows by capillary action from a sample application zone to contact a downstream test zone on the test strip, said downstream test zone containing an unlabelled immobile first reactant which reacts with the analyte if present to form an unlabelled reactant/analyte product;
 - ii. a second component separated from the first component and carrying a second, mobilizable, labeled reactant which is so placed on as to be moved into contact with the unlabelled reactant/analyte product to form a detectable unlabelled reactant/analyte/labeled reactant complex;

said first reactant and said second reactant being initially separate but in a spatial relationship such that they can be brought together after formation of the unlabelled reactant/analyte product to permit the reaction which forms the detectable unlabelled reactant/analyte/unlabelled reactant complex;

- b) contacting the sample application zone with the liquid sample such that the analyte moves to the test zone by capillary action to form a reaction product;

c) contacting the labeled reagent with the reaction product to form a detectable reaction complex.

[Claim 22] The method of claim 21 in which the assay device includes an absorbent sink on one of the components to facilitate the capillary movement of the liquid sample.

[Claim 23] The method of claim 21 in which the analyte is human chorionic gonadotropin.

[Claim 24] The method of claim 21 in which the liquid sample is selected from the group consisting of urine, blood, and saliva.

[Claim 25] The method of claim 21 in which the liquid sample is human blood.

[Claim 26] A test kit containing the device of claim 1 in packaged combination with instructions for use.

[Claim 27] A test kit containing the device of claim 14 in packaged combination with instructions for use.